

Opening Statement of Chairman Tom Davis
Committee on Government Reform
“One Year Later: Evaluating the Effectiveness of Project BioShield”
July 14, 2005

Good morning. I want to welcome everyone to today’s oversight hearing to assess the implementation of Project BioShield thus far. The purpose of this hearing is to consider whether the Project BioShield program is being adequately implemented to accelerate the research, development, and purchase of effective countermeasures against agents of bioterrorism.

Now that the Department of Health and Human Services (HHS) has begun to utilize its special authorities granted by Congress through the Project BioShield Act of 2004, the Committee feels it is time to review how these authorities are being executed. Specifically, the Committee will consider whether adequate medical countermeasures to protect our population against a biological attack are being procured.

As we tragically learned during the fall of 2001, our nation is vulnerable to biological terrorism. Letters laced with anthrax caused the deaths of five individuals, and thousands more had to be treated. The death toll could have been higher if there had not been effective countermeasures to treat that particular form of anthrax.

The “Project BioShield Act of 2004” gave the federal government better tools to develop and purchase vaccines and other drugs to protect Americans in the event of a bioterrorist attack. If the United States were to be attacked with these deadly pathogens, the need for the corresponding vaccines, tests, and treatments would be widespread and immediate.

The government has made some progress over the past year in implementing the BioShield program and improving preparedness efforts against bioterrorism. To date, DHS and HHS have determined that anthrax, botulinum toxins, smallpox, and radiological and nuclear agents pose a significant material threat to Americans and to U.S. national security. HHS has solicited and awarded contracts for medical countermeasures against these threats. In November 2004, HHS awarded a contract to VaxGen for up to 75 million doses of a new generation anthrax rPA vaccine, and in May awarded a contract for 5 million doses of the existing FDA licensed anthrax vaccine produced by BioPort Corporation. Additionally, HHS awarded a contract for pediatric potassium iodine in March of this year for inclusion within the Strategic National Stockpile.

In spite of these efforts, there remains some concern that HHS is moving too slowly to award contracts and has made insufficient efforts to stockpile existing countermeasures while new and improved ones are being developed. Among the questions we will ask today: How do we prepare against the threat of bioterrorism while waiting for new countermeasures to be researched and developed? Are we adequately linking threat assessments to the procurement of appropriate countermeasures? And, most importantly, are we safer now that we were before BioShield was enacted?

Witnesses on our second panel may raise concerns over the transparency of the solicitation process and whether companies are fully aware of how they are being evaluated and what certain terms and criteria are considered when HHS responds to a solicitation. We will also hear concerns today about whether the implementation of BioShield is working to erase barriers of entry to the bio-defense market and if more incentives are needed. I look forward to a robust discussion on whether the procurement of medical countermeasures to date has been sufficient and how best to work towards the improvements necessary for even greater preparedness.

Project BioShield needs to work. It was crafted so that the United States could better harness the power of the commercial marketplace to protect its citizens against threats, whether they be nuclear, or biological, or radiological, or what have you.

And, just one week after terrorists detonated four bombs in the heart of London, taking the lives of more than 50 people, no one should need a reminder of how real these threats are. Anyone who has read the 9/11 Commission Report, or has been listening to the experts who have studied these issues in depth, cannot help but understand this. I'd like to show a short video that is illustrative.

This is not an academic exercise. Project BioShield was conceived to help us face the most pressing threats facing our nation today, and we need it to live up to that promise. We have a fine selection of witnesses today and I look forward to their testimony.